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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,456	09/30/2003	Ralph N. Martins	520531-2001	5975
20999	7590	12/12/2007		
FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			EXAMINER STANDLEY, STEVEN H	
			ART UNIT 1649	PAPER NUMBER
			MAIL DATE 12/12/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/674,456

Applicant(s)

MARTINS, RALPH N.

Examiner

Steven H. Standley

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-39, 45 and 47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-39, 45, and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/26/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed 9/10/07 has been made of record. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Information Disclosure Statement

2. The Examiner thanks Applicant for submitting the Jobling et al. reference. The new IDS has been considered.

Rejections/Objections: Withdrawn

Specification

3. Applicant has overcome the rejection to the specification by providing the first page of the specification and a receipt -of-transmission.

Sequence Compliance

4. Applicant has amended claim 47 to include a SEQ ID NO. Therefore the Examiner withdraws the objection.

Claim Objections

5. Applicant has renumbered claims 37-39. Therefore the rejection for improper multiple dependencies is withdrawn.

Rejections/Objections: Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 27-39, 45, and 47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making the polypeptide of SEQ ID NO: 3 that binds a-beta, does not reasonably provide enablement for a pharmaceutical composition for the treatment of any disease or condition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the instantly claimed peptides in a pharmaceutical composition of the invention commensurate in scope with these claims. This rejection is maintained from the prior office action.

The prior rejection was over claim 45 alone, however applicant has amended base claim 27 to include a functional recitation of binding agents that are causative in disease. Therefore the examiner has rejected all the claims as not enabled.

Applicant argues that inclusion of the amendment in base claim 27 narrows the scope of the claim 45 such that is enabled and that the specification teaches the full scope of SOD related disease. This is not found persuasive because one of ordinary skill in the art would not recognize a polypeptide of 80% identity that would be useful for binding a causative agent of a disease or

disorder wherein the causative agent has or metal binding ability. Further, as argued and supported in the prior office action, not all peptides that bind a causative agent with SOD have therapeutic activity, and not all agents that have SOD activity are a-beta. Applicant is claiming the instant peptide binds to anything with SOD activity. Applicant has one example that the instant peptide binds to: a-beta. There is only one disease directly linked to a-beta, Alzheimer's disease. Superoxide dismutase (SOD) has SOD activity, and there is no evidence the peptide binds to it or that it would be useful if it did.

Finally, Applicant has not treated **one** disease in any art-accepted model of that disease, let alone the plethora of diseases that SOD might be associated with.

7. Claims 27-39, 45, and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained from the prior office action. The prior rejection was over claims 26-39, 45 and 47, not 26, and 28-39 as applicant has suggested in arguments under written description. See the top of page 6 of the prior office action, and read the second paragraph down also. Clearly claim 27 was rejected with all the rest.

Claims 27-39, 45, and 47 are to peptides of 80% identity to a peptide of SEQ ID NO: 3 and further deletion variants of that (for instance, claim 47). These

peptides still have no length limits and no requirements for any relation in sequence structure. One of skill in the art would not recognize any aspect of a peptide inasmuch as it would be selected by the method. Further, the claims that do recite sequence, 27-39, 45, and 47, recite "functional variants," or "peptidomimetics." The specification provides no definition or comprehensible boundaries for the term peptidomimetic and therefore they could be anything. Functional variants are defined broadly in the specification and is readable upon virtually any sequence (see the art rejections below).

Applicant argues that restricting the identity to 80% plus a functional recitation obviates the rejection. This is not found persuasive because the claims as written are readable upon fragments of the recited sequence as well as fragments with 80% identity. In addition, applicant has no written description of variants that share 80% identity with SEQ ID NO: 3.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 27-39, and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Wakasugi et al (1994).

Applicant argues that Wakasugi et al fail to teach any element of the claim because variants 80% identical to SEQ ID NO: 3 are now claimed. This is not found persuasive because claim 27 is not limited to the full-length of SEQ ID NO: 3 and can be a fragment thereof. Wakasugi et al teach an exactly matching trimer (RNR) of the SEQ ID NO: 3. Therefore, inherently the peptide would bind and act as the functional limitations indicate.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Standley whose telephone number is **(571) 272-3432**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are

unsuccessful, the examiner's supervisor, Jeffery Stucker can be reached on **(571) 272-0911**.

The fax number for the organization where this application or proceeding is assigned is **(571) 273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Steve Standley, Ph.D.
12/04/07


JEFFREY STUCKER
SUPERVISORY PATENT EXAMINER